

REMARKS:

Reconsideration of the rejections is respectfully requested.

The status of the claims is as follows:

Amended:	None
Cancelled:	None
New:	None
Pending:	42-103
Allowed:	None

1. Claim Rejections - 35 U.S.C. §102(e) - based on Denzer

Claims 42-3, 47-8, 50-1 and 55-6 stood rejected under 35 U.S.C. §102(e) based on an assertion of anticipation by Denzer, US 6,007,836. Applicant respectfully traverses.

All of the rejected claims recite that the delivery device not include a backing layer. The Office Action relies upon the teaching in Denzer of using the device described therein in conjunction with a condom, and asserts that this teaching amounts to teaching a lack of a backing layer. The text in Denzer (15:22-30) relied upon by the Office Action reads:

The further condom-embodiments of the present invention are similar to each other in that the transdermal patch has no at least one outer, impermeable barrier layer. The wall of the condom itself serves as the barrier, preventing leakage of the vasodilator. As a result, in both the further condom-embodiments, *the patch must remain anchored to the inner wall of the condom*, so that removal of the condom will result in removal of the patch containing vasodilator as well.

(Emphasis added.) As a review of this cited text unambiguously establishes, Denzer teaches a patch permanently affixed to a condom. Thus, the condom is the backing layer. Accordingly, the rejection based on Denzer, as framed, is in error and should be, it is respectfully submitted, withdrawn.

Examining Denzer in greater detail, one observes the critical importance ascribed in the Denzer specification to keeping the medicament of the patch away from the second sex partner. See, 1:19-21; 2:57-8; 3:68-4:4; 7:56-63; 8:12-6; 8:23-5. Thus the role of the condom as a backing layer is critical pursuant to the teachings of Denzer.

Reviewing the detailed description of Denzer's condom embodiments as described in the paragraphs preceeding the text cited by the Office Action, one finds another condom embodiment that is instructive on the importance of a backing layer. That embodiment weakly adheres a patch to the inner surface of a condom, so that the user can transfer the patch from the condom to the skin of user's penis. However:

As with the non-condom embodiments of the present invention, the construction of the patches in these various condom-embodiments is designed to prevent the vasodilator material from contacting the skin of the female during use. Even though the transdermal patch [of this particular embodiment] can detach from the inner wall of the condom, *each patch is constructed with an impermeable barrier layer* which comprises the at least one outer layer of each respective condom embodiment, and the adhesive that anchors the patch to the skin of the penis is designed to remain adhered to the skin of the penis, preventing any lateral leakage of the vasodilator.

Col. 14:55-65 (emphasis added, explanatory note in brackets added).

Thus, in view of the criticality, from the Denzer perspective, of keeping the medicament away from the second sex partner, there is never an embodiment that does not use a backing layer, irrespective of what word is used to name the backing layer.

Accordingly, the rejection is in error. Applicant respectfully requests that the rejection be withdrawn.

2. Claim Rejections - 35 U.S.C. §103(a) - based on Denzer

Claims 42-4, 47-8, 50-7, 60-6 and 80-5 stood rejected under 35 U.S.C. §103(a), based on an assertion of obviousness over Denzer. This rejection is respectfully traversed.

As a preliminary matter, Applicant respectfully notes that the claims in question do not recite rigidity. Accordingly, Applicant cannot identify any relevance for the discussion in the Office Action of this term.

As to claims 42-4, 47-8 and 50-6, the fundamental flaw in the rejection discussed above addresses this rejection.

As to claims 57, 60-6, and 80-5, the Office Action does not identify, and a review of Denzer could not identify, any disclosure relevant to “the disk comprises 70 to 95 wt% filmogenic polymer.”

A portion of the Office Action discusses the criticality of excluding the backing and release layer, but to what purpose is this discussion added? Criticality is a concept whose relevance can arise with respect to amount ranges that are close to those in the art. Here the claims recite a feature that is obviously important in the cited prior art. The concept of criticality is not relevant.

Moreover, as mentioned at MPEP 2143.02, a proposed modification in the prior art cannot render that art, as modified, unsatisfactory for its intended purpose. The patch of Denzer is intended to rigorously prevent medicament from being surface exposed on the user, as discussed above. The modified device is thus unsatisfactory. The patch of Denzer has a contact adhesive and thus needs a release layer, which is provided in all Denzer embodiments (7:41-3). Eliminating the release layer renders the device unsatisfactory.

In light of the above discussion, Applicant respectfully submits that the rejection should be withdrawn.

3. Claim Rejections - 35 U.S.C. §103(a) - based on Denzer, Yamamura

Claims 45, 58, 69-76 and 78-9 stood rejected under 35 U.S.C. §103(a), based on an assertion of obviousness over Denzer in view of Yamamura, US 5,914,118. This rejection is respectfully traversed.

Yamamura is said to teach the equivalence of PVP and karaya adhesives. Assuming this equivalence for the sake of argument, nonetheless nothing teaches PVP use in a device as claimed, which is not taught or suggested in Denzer, as discussed above.

4. Claim Rejections - 35 U.S.C. §103(a) - based on Denzer, Postaire

Claim 46 stood rejected under 35 U.S.C. §103(a), based on an assertion of obviousness over Denzer in view of Postaire, FR 2710649. This rejection is respectfully traversed.

Postaire is said to teach that gliadin gel can be used in a patch, and can be used to optimize adhesive properties. Since the abstract of the citation discusses *non-adhesive* films, the examiner is asked to provide through the Office's translation services the teachings indicated in the Office Action. Absent a basis for analyzing the rejection, Applicant does not have sufficient information for a more detailed response. Should the Office provide sufficient information in the next Office Action, Applicant respectfully submits that the action should be non-final so that Applicant has its chance at a substantive response.

5. Claim Rejections - 35 U.S.C. §103(a) - based on Denzer, Place

Claims 49 and 59 stood rejected under 35 U.S.C. §103(a), based on an assertion of obviousness over Denzer in view of Place, US 5,773,020. This rejection is respectfully traversed.

Place is asserted to teach misoprostol to treat erectile dysfunction. Applicant respectfully submits that nothing suggests administering misoprostol in the claimed disk without backing layer. Accordingly, Applicant respectfully submits that the rejection should be withdrawn.

6. Claim Rejections - 35 U.S.C. §103(a) - based on Denzer, Yamamura, Place

Claim 68 stood rejected under 35 U.S.C. §103(a), based on an assertion of obviousness over Denzer in view of Yamamura and Place. This rejection is respectfully traversed.

Applicant respectfully submits that this rejection is addressed by the discussion above.
Applicant respectfully submits that the rejection should be withdrawn.

7. Claim Rejections - 35 U.S.C. §103(a) - based on Denzer, Smith

Claims 86-9, 91-4, and 99-101 stood rejected under 35 U.S.C. §103(a), based on an assertion of obviousness over Denzer in view of Smith, US 6,001,380. This rejection is respectfully traversed.

Smith is said in the Office Action to teach wetting the skin to promote adhesion of a transdermal device. However, the most relevant teaching is “The compositions are *released from the sheet* when the sheet is contacted with wet skin so as to apply a film of a mixture of the dermatological agents to the skin.” Col. 2:51-4 (emphasis added). Thus, Smith does not appear to be about wetting to promote adhesion of a patch. An electronic search of Smith finds no more relevant disclosure containing “wet”. Accordingly, Applicant respectfully submits that the rejection should be withdrawn.

8. Claim Rejections - 35 U.S.C. §103(a) - based on Denzer, Smith, Place

Claim 90 stood rejected under 35 U.S.C. §103(a), based on an assertion of obviousness over Denzer in view of Smith and Place. This rejection is respectfully traversed.

Applicant respectfully submits that this rejection is addressed by the discussion above.
Applicant respectfully submits that the rejection should be withdrawn.

9. Claim Rejections - 35 U.S.C. §103(a) - based on Denzer, Smith, Postaire

Claims 96-8 stood rejected under 35 U.S.C. §103(a), based on an assertion of obviousness over Denzer in view of Smith and Postaire. This rejection is respectfully traversed.

Applicant respectfully submits that this rejection is addressed by the discussion above.
Applicant respectfully submits that the rejection should be withdrawn.

10. Claim Rejections - 35 U.S.C. §103(a) - based on Denzer, Smith, Yamamura

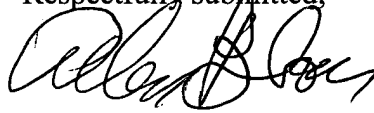
Claims 96-8 stood rejected under 35 U.S.C. §103(a), based on an assertion of obviousness over Denzer in view of Smith and Yamamura. This rejection is respectfully traversed.

Applicant respectfully submits that this rejection is addressed by the discussion above. Applicant respectfully submits that the rejection should be withdrawn.

Conclusion

In light of these amendments and remarks, it is respectfully submitted that the Amendment should be entered, the rejections should be withdrawn, and that the application is in condition for allowance.²

Respectfully submitted,



Allen Bloom
Registration No. 29,135



A Pennsylvania Limited Liability Partnership
Princeton Pike Corporate Center
PO Box 5218
Princeton, New Jersey 08543-5218
Allen Bloom (609) 620-3214
Fax: (609) 620-3259
Attention: Allen Bloom

² **FEE DEFICIENCY**

IF ANY ADDITIONAL EXTENSION IS REQUIRED, PLEASE CONSIDER THIS PAPER A PETITION FOR SUCH AN EXTENSION; ANY FEE FOR THE EXTENSION REQUIRED FOR CONSIDERATION OF THIS PAPER BUT NOT ENUMERATED ABOVE OR IN A TRANSMITTAL OR OTHER ASSOCIATED PAPER CAN BE CHARGED TO ACCOUNT NO. 04-0480.

AND/OR

IF ANY ADDITIONAL FEE IS REQUIRED FOR CONSIDERATION OF THIS PAPER, PLEASE CHARGE ACCOUNT NO. 04-0480.